REMARKS

This is in response to the Office Action dated August 20, 2001, rejecting claims 1 to 24, all of the claims in the case. Pursuant to a Petition for Extension of Time, enclosed herewith, a response is due February 20, 2002.

Enclosed herewith, is a marked up version of the changes made to the specification (including the claims), entitled "VERSION WITH MARKINGS TO SHOW CHANGES MADE". Claims 1, 2 and 12 have been amended. Claims 6, 7 and 9 have been rewritten in independent form.

A transmittal cover letter and corrected Figures 1 and 2 are submitted herewith in response to the Official Draftsperson' Patent Drawing Review.

Claims 1-16, 18, 21 to 24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The word "low" in claim 1 has been replaced with "an aqueous solubility below 100 μg/ml". The phrase "one or more" has been added to clarify the requirement for the tabletting agents in claim 1. The word "adapted" has been deleted from claim 2 and the phrase "can be used" substituted therefor. Similarly, the phrase "is suitable for sterilization" has been deleted from claim 12 and the phrase "can be sterilized" substituted therefor. As amended claim 12 now unambiguously and definitely recites "an implant as claimed in claim 1 which can be sterilized, or has been sterilized, by irradiation." No new matter has been added by the present amendments to the claims. In view of the present amendments to the claims the rejection under 35 U.S.C. § 112, second paragraph, should be withdrawn.

Claim 21 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner states that there is insufficient guidance for one in the art to know when this implant is needed as opposed to any other treatment modality. Applicant respectfully traverses for the following reasons. Applicant submits that the knowledge needed to determine when the implant described in the present application is needed as opposed to any other treatment modality is not relevant to enable one of skill in the art to use the claimed method. The claimed method of treatment for parasitic infections does not require a comparison to other modes of administration; but rather only an understanding of the nature of a particular parasitic infection and the appropriate implants as described in the

application. Nonetheless, Applicant submits that one of skill can readily determine if the claimed method is appropriate treatment for parasitic infections in animals, either alone or in conjunction with other known and available modes of treatment. As described in the specification, there is need for formulations that are convenient to administer and which provide prolonged protection against parasites. The present invention provides such a formulation prepared and used as described on page 2, line 22 to page 7, line 16 of the specification. The present application therefore provides adequate description of how to make the implant and use it to treat animals for parasitic infections as claimed and the rejection under 35 U.S.C. § 112, first paragraph should be withdrawn.

Claims 1 to 5, 8, 10, 12 and 14 to 2? (the last claim referred to is not legible, but it is assumed in this response to include the last claim in the application, that is, claim 21; clarification is requested), are rejected under 35 U.S.C. § 102(b) as being anticipated by Hsu et al. EPO 537998. Claims 6, 7 and 9 have been re-written in independent form. Hsu describes a drug delivery device compounded of a polymeric matrix, a vehicle (which is a plasticizing solvent for the polymeric matrix) and a drug. The drug may be an avermectin or a milbemycin, and the device is particularly intended for topical delivery of drugs, such as a flea or tick collar for pets. The present invention is directed to a solid implant useful for prolonged treatment by release of the active drug in an intramuscular or subcutaneous mode and not topically, such as is the case with a device such as a flea or tick collar. Hsu refers in a single instance, and in a broad, general statement, to a subcutaneous implant on page 3, line 15. However, no enabling description is provided with respect to a solid implant or its use in treating parasitic infection as claimed in the present application. Absent further description and support, Hsu fails to provide sufficient disclosure for one to make or use the present invention. The present invention claims a solid implant comprising at least one parasiticidal compound having an aqueous solubility below 100 μg/ml; and one or more tabletting excipients including a bulking agent. As noted by the Examiner, nowhere do Hsu et al. describe one or more tabletting agents as a component of the device described in EP 537998. Furthermore, nowhere does Hsu describe implantation into cattle ears as acknowledged by the Examiner. In view of these remarks, Hsu does not anticipate the present invention and the rejection under 35 U.S.C. § 102(b) should be withdrawn.

Claims 1 to 3, 8, 10-16 and 20 to 2? (the last claim referred to is not legible, but it is assumed in this response to include the last claim in the application, that is, claim 21; clarification is requested), are rejected under 35 U.S.C. § 102(b) as being anticipated by Senbo-5567429. Claims 6, 7 and 9 have been re-written in independent form. Senbo

describes a pest controlling composition for topical aerosol formulation, as an orally administered formulation or as part of a pest controlling collar for pets. Nowhere does Senbo mention or suggested a solid implant as claimed or its use in treating parasitic infections in animals. Absent any mention of such implants, Senbo does not anticipate the present invention. The Examiner submits that the formulations described by Senbo are adaptable and suitable for implantation and irradiation. Applicants note that the words "adaptable" and "suitable" have been deleted from the claims by the present amendment. The Examiner's comments concerning future intended use have therefore been obviated. In view of the present amendment and remarks, the rejection under 35 U.S.C. § 102(b) should be withdrawn.

Claims 1-24 (?; the last claim referred to is 24, but it is assumed in this response to include the last claim in the application, that is, claim 21; clarification is requested), are rejected under 35 U.S.C. § 103(a) as being unpatentable over Shih et al. EPO 473223 in view of Hsu, Roorda 5543156 and Senbo.

Hsu and Senbo taken alone or in combination do not mention or suggest the solid implants and methods of treatment claimed in the present invention for the same reasons provided above. Hsu fails to provide an enabling disclosure with respect to solid implants and Senbo fails to mention implants at all.

The primary reference, Shih et al., describes a bioerodable implant comprising either a poly(orthoester) or a polyacetal. The implants described by Shih et al. are highly specialized and of unique design and the beneficial drug must be subject to condensation with diketene acetals or divinyl ethers and the drug is covalently linked with the polymer chain backbone. This type of implant is entirely different from that of the present invention, which simply comprises a solid implant comprising at least one parasiticidal compound having an aqueous solubility below 100 μg/ml and one or more tabletting excipients including a bulking agent.

Roorda describes a bioerodable device comprising a polymer or polymers together with a required excipient that is not pore forming. The design of the device is particularly intended for diffusional release of active agents. Nowhere does Roorda mention or suggest a solid implant comprising at least one parasiticidal compound having an aqueous solubility below 100 μg/ml and one or more tabletting excipients including a bulking agent.

Even if Shih et al. were combined with the descriptions provided in Hsu, Roorda 5543156 and Senbo, the present invention would not result. The Examiner comments that it would have been obvious to use Shih and Hsu implants, modified as desired to optimize

production as shown by Senbo and Roorda. Yet Shih and Hsu each describe devices that are highly specialized and entirely different in design from the present invention. The present invention is not an optimization of either Shih or Hsu, but rather a solid implant which is much simplified over the cited references and is particularly suited to convenient administration for prolonged protection. The implant of the present invention is produced using simple methods as described in the specification and does not require prior chemical reaction of the active drug or covalent attachment of the drug to a polymeric backbone. While the use of various bulking agents or antioxidants may have been known for use in various parasiticidal formulations, none of the cited references, taken alone or in combination describe the particular combination of elements presented in the claims of the present invention. It would not have been obvious to combine those particular elements from the cited references, such as Senbo and Roorda without any suggestion to do so, and it would not have been obvious that the combination as claimed in present invention would be useful in treating parasitic infections in view of the simplicity of manufacture and design. The rejection under 35 U.S.C. § 103(a) should therefore be withdrawn.

In view of the present amendment and remarks, Applicant believes the present application contains patentable subject matter and respectfully requests a timely Notice of Allowance be issued for claims 1-24, all of the claims in the application.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

1. (amended) A solid implant comprising at least one parasiticidal compound having [low] an aqueous solubility below 100 µg/ml; and one or more tabletting excipients including a bulking agent.

2. (amended) An implant as claimed in claim 1, which is [adapted] can be used for subcutaneous implantation.

Delete claim 3.

6. (amended) [An implant as claimed in [any one of the preceding claims,] claim 1 wherein the bulking agent is lactose.] A solid implant comprising at least one parasiticidal compound having an aqueous solubility below 100 µg/ml; and one or more tabletting excipients including a bulking agent, wherein the bulking agent is lactose.

7. (amended) [An implant as claimed in claim 1 wherein the tabletting excipients include magnesium stearate.] A solid implant comprising at least one parasiticidal compound having an aqueous solubility below 100 µg/ml; and one or more tabletting excipients including a bulking agent, wherein the tabletting excipients include magnesium stearate.

12. (amended) An implant as claimed in claim 1 which [is suitable for sterilization] can be sterilized, or has been sterilized, by irradiation.